MISSOURI BOARD OF PHARMACY
NEWSLETTER

FEBRUARY 2017

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ANNUAL REPORT

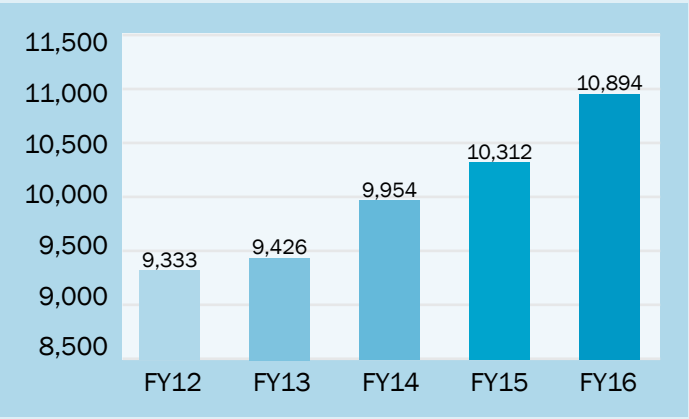
The Board's annual report for Fiscal Year 2016 (FY16) is now available online. As reflected in the following excerpts, the Board had another successful fiscal year:

LICENSING

- The total licensee/registrant count increased approximately 2.9% from 35,174 licensees/registrants in FY15 to 36,189 licensees/registrants in FY16 as reflected below:

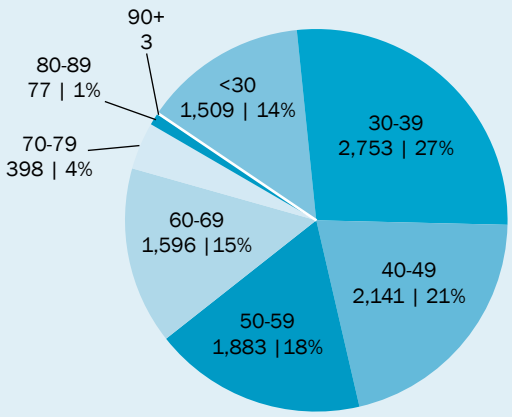
LICENSING TOTALS	
Drug Distributors (licensed and temporary)	1,377
Drug Distributor Manufacturer Registrants	97
Intern Pharmacists	1,930
Pharmacists (active and inactive)	10,894
Pharmacies (instate, non-resident and temporary)	2,636
Pharmacy Technicians	19,255
Total	36,189

- Total licensed pharmacists (active and inactive) increased 5.64% to 10,894 as follows:



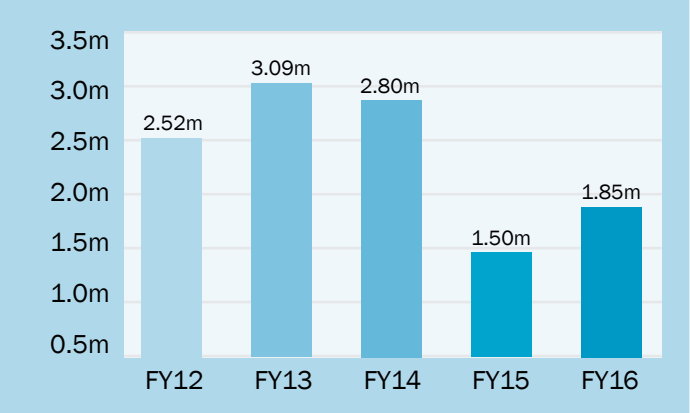
- Forty-one percent (41%) of licensed Missouri pharmacists are age 39 and under with the remaining fifty-eight percent (58.8%) at age 40 or above. 54% of active pharmacists were male and 46% were female.

(Pharmacist Distribution by Age)



FINANCIAL OPERATIONS

- The Board continues to monitor its fund balance and has approved lower renewal fees for all license categories over the last several fiscal years. As part of this initiative, pharmacy and drug distributor renewal fees were lowered in FY 16 from $ 450 to $150. Despite the decrease, the Board experienced a 23.3% increase in revenue as reflected below:



- The Board will continue to monitor revenue and decrease fees as needed. Significantly, renewal fees for pharmacists and intern pharmacists were decreased to $50 in FY17. The FY17 technician renewal fee has also been lowered to $10.

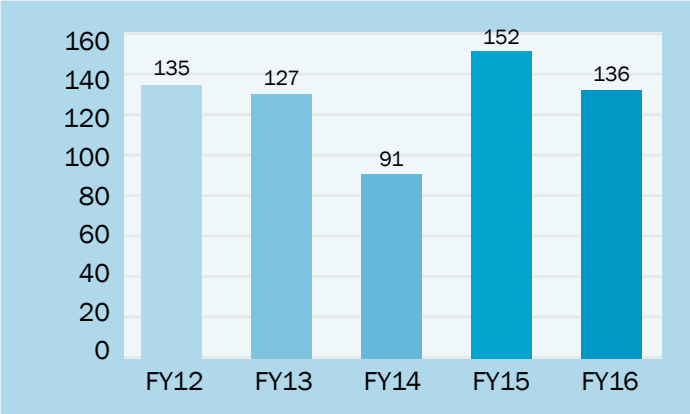
COMPLAINTS

- The Board received/opened 719 new complaints in FY 16- 554 complaints were practice-related (77%) while 165 were non-practice related Missouri Department of Revenue tax compliance cases (approx. 23%).
- Of the 554 practice-related complaints:
  - 12% involved disciplinary action in another state [68]
  - 8.6% involved dispensing errors [15] or improper dispensing [33]
  - 7% involved drug diversion [9], loss of drugs [12] or theft of drugs [18]
  - 6.3% involved immunization/administration [35]
  - 1.6% involved compounding [9]

DISCIPLINARY ACTIONS
(NUMBERS DO NOT INCLUDE TAX SUSPENSIONS)

- Total practice related disciplinary actions decreased 10.5% from FY15 as follows:

(Practice related disciplinary actions by FY)



- Of the 136 practice-related cases, disciplinary action was taken against 94 pharmacy technicians, 27 pharmacists, 14 pharmacies and 1 drug distributor.

A complete copy of the FY16 annual report is available on the Board's website at: http://pr.mo.gov/boards/pharmacy/annualreports/2016%20Annual%20Report.pdf

TECHNICIAN RENEWALS

It's renewal time! Pharmacy technician renewals will be mailed on March 1st. Don't wait until the last minute! Registrations must be processed and completed by the Board office by May 31st. Avoid delays and renew online. The Board has decreased the technician renewal fee to $ 10.

NEW MISSOURI DRUG COLLECTION, TAKE-BACK RULE

The Board continues its efforts to combat prescription drug abuse. An important part of this effort is reducing the availability of unwanted prescription drugs by providing safe ways for patients to destroy unwanted medication. In line with this goal, the Board has promulgated rule 20 CSR 2220-2.095 which will allow Missouri licensed pharmacies to collect medication from the public for destruction.

The new rule is effective on March 30, 2017 and contains detailed requirements for pharmacies interested in operating

a drug collection program. The following is a basic summary of the new rule provisions for Missouri pharmacies:

- Pharmacies may provide a collection receptacle or establish an authorized mail-back program to accept medication from the public. Board notification or registration is not required. However, participating pharmacies must establish and follow policies and procedures for collecting/destroying medication as required by the rule. Participation is voluntary; pharmacies are not required to establish a drug collection program.
- Collected medication must be destroyed and cannot be resold or reused under any circumstances.
- Medication may be accepted from any member of the public (see below for controlled substances). However, collection receptacles or mail-back programs cannot be used to dispose of unused/unwanted medication in the pharmacy's inventory (e.g., expired medication, medical waste).
- Collection receptacles must be securely placed and maintained inside the pharmacy's physical building in a manner that prevents theft, diversion or unauthorized removal. Receptacles must be securely locked, substantially constructed containers that are equipped with inner liners for storing medication. Receptacles must be visible to pharmacy staff at all times and may not be located in or near exit doors.
- For mail-back programs, the public must be provided pre-addressed, postage-paid mail-back packages for returning medication. Mail-back packages must be nondescript and cannot include any markings or other information that might indicate the packages contain medication. Each package must include a unique identification number or other unique identifier to enable tracking.
- Mail-back packages cannot be returned to the pharmacy. Instead, packages must be directly mailed to a collector that is authorized by the DEA or other federal law to destroy medication (e.g., a reverse distributor). Consumers cannot be required to provide personally identifiable information when mailing back medication.
- Collection receptacles may be placed at a long-term care facility for use by the public or facility residents. The new rule does not apply to medication collected for return and reuse as authorized by the Board's return and reuse rule (20 CSR 2220-3.040).
- Collected medication must be rendered non-retrievable and destroyed in compliance with all applicable federal and state laws. Destruction may occur at the pharmacy or medication may be transferred offsite for destruction by an entity authorized to destroy medication under state and federal law.
- Destruction records and inventories of inner-liners must be maintained for two (2) years and available on inspection/request (see rule for specific recordkeeping requirements).
- The rule does not apply to or restrict licensees/permit holders from participating in medication collection programs operated by law enforcement agencies (e.g., DEA or police/sheriff "take back" days), provided: (1) law enforcement personnel are present whenever drugs are collected or on-site, (2) collected medication is placed into a collection container that is supervised by law enforcement at all times and, (3) collected medication remains under the control of, and is removed by, law enforcement.

What about controlled substances? The Bureau of Narcotics and Dangerous Drugs ("BNDD") has informed the Board that BNDD is in the process of revising its rules to align with DEA standards for collecting controlled substances for destruction. Additionally, § 195.070.4, RSMo, provides a pharmacy "shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug." Pending final rulemaking, BNDD recommends that licensees consult with legal counsel to ensure compliance with state and federal law, including, the DEA's Disposal of Controlled Substances rule.

This list is not exhaustive; additional requirements exist that are not listed above. Licensees should review the entire rule to ensure compliance. 20 CSR 2220-2.095 is available on the Board's website at: http://pr.mo.gov/pharmacists-rules-statutes.asp

RULE REVIEW

Governor Eric R. Greitens recently issued Executive Order 17-03 which requires state agencies to review all rules under their jurisdiction. As part of the review, state agencies are required to hold at least two (2) public hearings to allow citizens and businesses to identify regulations that are ineffective, unnecessary or unduly burdensome.

In compliance with Executive Order 17-03, the Board will be holding public hearings during the following regularly scheduled meetings to receive comments from the public:

APRIL 19
9:30AM

Courtyard Columbia
3301 Lemone Industrial Blvd.
Columbia, MO

JULY 12
9:30AM

Courtyard Columbia
3301 Lemone Industrial Blvd.
Columbia, MO

Public comments will be accepted on any of the Board's rules. Due to time restraints, comments may be limited to three (3) minutes per person. Comments may also be submitted online at: https://renew.pr.mo.gov/pharmacists-proposed.asp.

What about the Board's rule review that was announced in 2016? The Board's rule review initiative will be jointly conducted with the review required by Executive Order 17-03. The Board will take general comments on any rule at the meetings listed above and then take specific comments on the rules identified on the Board's rule review calendar which is available online at: http://pr.mo.gov/boards/pharmacy/RuleReviewCalendar.pdf

The following specific rules will be reviewed at the Board's upcoming April meeting *(in addition to the general public comment period):*

APRIL 2017

20 CSR 2220-2.140	Prescription Services by Pharmacists/Pharmacies for Residents in Long-Term Care Facilities
20 CSR 2220-2.085	Electronic Transmission of Prescription Data
20 CSR 2220-2.145	Minimum Standards for Multi-Med Dispensing
20 CSR 2220-6.060	General Provisions
20 CSR 2220-6.070	Certificate of Medication Therapy Plan Authority
20 CSR 2220-6.080	Medication Therapy Services By Protocol

Again, comments on the above rules may be submitted online at: https://renew.pr.mo.gov/pharmacists-proposed.asp

COMPLIANCE CORNER

The Board is routinely asked about Board notification requirements. The following chart lists the most common notification requirements for Board licensees/registrants:

ALL LICENSEES

What?	When?	Cites	Online Notification?	Application Online?
Final adverse action by another state, jurisdiction or governmental agency against any license to practice as a pharmacist, pharmacy, intern pharmacist, technician, drug distributor or drug outsourcing facility	** Rule does not designate a timeframe; Notification within seven (7) days is requested.*	§ 338.075, RSMo	✔	
Any exclusion to participate in any state or federally funded health care program for fraud/ abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicaid, Medicare)	** Rule does not designate a timeframe; Notification within seven (7) days is requested.*	§ 338.075, RSMo	✔	

DRUG DISTRIBUTORS

What?	When?	Cites	Online Notification?	Application Online?
Change of Manager-In-Charge (MIC)	Immediately	20 CSR 2220-5.030(2)(E)		✔
Change of Ownership (Any individual or entity owning 25% or more of the pharmacy)	Within thirty (30) days of acquiring the percentage of ownership.	20 CSR 2220-5.020(5)(B)		✔

Termination of Business	Within fifteen (15) days after termination	20 CSR 2220-5.025(1)		✔
PHARMACISTS				
What?	**When?**	**Cites**	**Online Notification?**	**Application Online?**
Address Change	** Rule does not currently specify a timeframe; Prompt notification is requested.*	20 CSR 2220-2.010(1)(N)	✔	
Employment Change	Within fifteen (15) days of change	20 CSR 2220-2.010(1)(Q)	✔	
Notification of Intent (Immunizations)	Annually (calculated from the date the NOI is filed from with the Board)	20 CSR 2220-6.050(4)(G)	✔	
Notification of Intent (Administration by Prescription Order)	Annually (calculated from the date the NOI is filed from with the Board)	20 CSR 2220-6.040(3)(F)	✔	
Pharmacist-in-Charge Change (former PIC)	Immediately	20 CSR 2220-2.010(1)(M)		✔
PHARMACY				
What?	**When?**	**Cites**	**Online Notification?**	**Application Online?**
Change of Pharmacy Classification	Prior to performing the additional services or promptly after terminating any classification activity *(Application Required)*	20 CSR 2220-2.020(10)		✔
Location/Address Change	Prior to operating at new location *(Application required)*	20 CSR 2220-2.020(4)		✔
Name Change	Prior to operating under new name *(Application required)*	§ 338.220		✔
Change of Ownership (Any individual or entity owning 25% or more of the pharmacy)	Within thirty (30) days of acquiring the percentage of ownership. *(Application Required)*	20 CSR 2220-2.020(3)(C)		✔
Class-M Pharmacies- Specialty Bleeding Disorder (Notification of intent to provide legend blood-clotting products for bleeding disorder patients)	Annually on or before January 31st	20 CSR 2220-6.100(3)(A)	✔	
Disciplinary action against a pharmacist or the voluntary resignation of a pharmacist against whom a complaint/ report has been made which might have led to disciplinary action.	Within fifteen (15) days of the final disciplinary action/ voluntary resignation	§ 338.133, RSMo	✔	
Pharmacy change in partners/members of a limited liability partnership or a limited liability company.	Within ten (10) days after the change	20 CSR 2220-2.020(3)(B)		✔
Pharmacist-in-Charge Change	Immediately	20 CSR 2220-2.010(1)(M)		
Recall (Non-sterile Compounding)	Within three (3) business days of the recall	20 CSR 2220-2.400(8)(C)2.		

Recall (Sterile Compounding)	Within three (3) business days of the recall	20 CSR 2220-2.200(21)		
Remodeling	Thirty (30) days before remodel begins	20 CSR 2220-2.020(4)		
Security Breach (Offsite Storage Facility)	Within fifteen (15) days of breach	20 CSR 2220-2.010(J)(1)		
Sterile Compounding: Detection of a highly pathogenic microorganism in any sterile preparation or environmental monitoring/testing.	Within seven (7) days of detection	20 CSR 2220-2.200(20)(B)		
Technician Disciplinary Action	Within fifteen (15) days of action	20 CSR 2220-2.010(1)(P)	✔	
Termination of Business	Within fifteen (15) days after termination	20 CSR 2220-2.015(1)		✔

TECHNICIANS

What?	When?	Cites	Online Notification?	Application Online?
Address Change	** Rule does not currently specify a timeframe; Prompt notification is requested.*	20 CSR 2220-2.013(2)	✔	
Employment Address Change	Within fifteen (15) days of change	20 CSR 2220-2.700(3)	✔	

- *Online notifications can be submitted at: http://pr.mo.gov/pharmacists-onlineservices.asp. Licensees should independently review the Board's rules and statutes to ensure full compliance.*

STERILE COMPOUNDING CORNER

Final Sterile Compounding Rule - Effective 1/30/2017

The final 20 CSR 2220-2.200 *Sterile Compounding* rule became effective 1/30/2017, replacing the interim emergency rule that had been in effect since 8/4/2016. The final rule is similar to the emergency rule with a few revisions. A summary of the major revisions regarding environmental sampling, remedial investigations, and aseptic technique skill assessments are listed below. Please review the entire rule to ensure full compliance.

- (10) Aseptic Technique Skill Assessment
  - Individuals who fail visual observation of hand hygiene, garbing or aseptic technique must pass a re-evaluation in the deficient area before they can resume compounding. (The emergency rule required 3 re-evaluations)
  - Individuals who fail media fill testing must pass 3 successive media fill tests prior to resuming compounding
  - Self-observation is not allowed. An individual may not perform a visual evaluation on themselves.
- (18) Environmental Sampling/Testing
  - Volumetric air sampling is required every 6 months for all risk levels
  - Surface sampling is required every 6 months for risk level 2 compounders
  - Surface sampling is required every 30 days for risk level 3 compounders
- (20) Remedial Investigations
  - Compounding needs to cease when:
- CFU counts exceed USP 797 action levels in an ISO 5 or ISO 7 area
- A highly pathogenic microorganism is detected in an ISO 5 or ISO 7 area (regardless of the CFU count)
  - Compounding may resume when resampling shows a suitable state of microbial control in the ISO 5 or ISO 7 area.

Pharmacists-in-charge should review their policies and procedures manual to determine if any revisions are needed to accommodate the above requirements.

REMEDIAL INVESTIGATIONS

20 CSR 2220-2.200 Sterile Compounding Section (20) requires pharmacies to conduct remedial investigations when:

- Any required sampling or testing demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels

OR

- A highly pathogenic microorganism is detected in any preparation or ISO classified area (e.g. Gram negative rods, coagulase positive staphylococcus, molds, fungus or yeast).

Actions to be taken during a remedial investigation include:

- Quarantine the affected area and any sterile preparations/ ingredients that were prepared or used within the compounding process until the results of the investigation are known.
  - If the affected area is within an ISO 5 or ISO 7 classified area, compounding must **STOP** in that area while the remedial investigation is conducted.
  - Compounding may resume once resampling demonstrates a microbial state of control
- Identify potential sources of the microorganism(s) and take corrective action
- Resample the affected area(s)
- Document the events:
  - If a highly pathogenic microorganism is found, the pharmacy must notify the Board in writing within 7 days *regardless of the CFU count.*
  - Notifications may be emailed to Katie.Debold@pr.mo.gov or mailed to the Board office
  - Notifications should include details surrounding the remedial investigation, sampling results, and any corrective actions taken
  - Keep a record of all corrective actions taken during the remedial investigation including the resampling results

Policies and procedures manuals for **ALL** pharmacies performing sterile compounding must encompass remedial investigations.

Additional sterile compounding guidance documents and webinars are available on the Board's website.

GOLD CERTIFICATES

The following pharmacists have maintained a Missouri pharmacist license for 50 years. Congratulations to our newest "gold-certificate" pharmacists:

Robert L Bossler
John W Foxworth
James P Hess
John L Keller

DISCIPLINARY ACTIONS

PHARMACISTS:

Shannon M. Krieg, #2005000313, O'Fallon, MO. Revoked, and cannot reapply for seven (7) years. Violation of discipline, failed to meet with the Board at requested meetings, failed to submit to a urine sample for drug testing, positive hair sample test. Section 338.055.2(5), (6), (13), and (15), RSMo

Erin E. Thomas, #2005011039, St. Louis, MO. Three (3) years probation. As staff pharmacist, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and record keeping violations. Section 338.055.2 (5), (6), (13), and (15), RSMo.

Britini Weaver, #2007011416, Palmyra, MO. Probation for two (2) years. As staff pharmacist, verified and dispensed prescriptions for pseudoephedrine not lawfully authorized by the doctor. Failure to report pseudoephedrine sales to the Missouri electronic pseudoephedrine tracking system. Record keeping violations, improperly labeled prescriptions. Section 338.055.2(6), and (15) RSMo.

Michael A. Wilczek, #041144, Albany, MO. Public Censure. As Pharmacist-In-Charge, administered vaccines prior to signing the protocol. Section 338.055.2(5), (6), (13), and (15), RSMo.

PHARMACIES:

Wickliffe Veterinary Pharmacy, #2010015142, Lexington KY. Probation until 10/23/2018. Discipline in another state: Entered into an Agreed Order with the Kentucky Board of Pharmacy for sterile and non-sterile compounding violations, allowing technicians to work unsupervised and improper storage of compounded preparations. Controlled substance prescriptions dispensed utilizing a prescriber whose license and/or DEA registration was not current. Entered into a Consent Order with the Oregon, Alabama, Colorado, and Texas Boards of Pharmacy based on the discipline imposed by the Kentucky Board of Pharmacy. Section 338.055.2 (5), (8), and (13), RSMo.